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September 23, 2021

BY ECF & OVERNIGHT MAIL

Honorable Freda L. Wolfson
Chief United States District Judge
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street Court, Room 5E
Trenton, New Jersey 08608

Re: *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services, et al.*, Civil Action No. 3:21-cv-634

Dear Chief Judge Wolfson:

Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") respectfully notifies the Court of two material developments relevant to this case.

First, and most recently, on September 22, 2021, Defendant Health Resources and Services Administration ("HRSA") referred Sanofi's "continued failure to provide the 340B price to covered entities utilizing contract pharmacies" to "the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule." *See* Exhibit A. This sets in motion the possible imposition of civil monetary penalties ("CMPs") on Sanofi in connection with its 340B integrity initiative. Indeed, in its May 17 letter to Sanofi that is being challenged in this action and that forms the basis for this OIG referral, HRSA already announced its final determination that Sanofi's integrity initiative violated Section 340B. Rather than wait for this Court to rule on the fully briefed dispositive motions regarding the permissibility of Sanofi's program, HRSA has taken another step toward imposing potentially massive financial penalties—simply because Sanofi is continuing to operate its program while awaiting judicial resolution of the matter. This is all the more remarkable because, after HRSA sent its May 17 letter first threatening Sanofi with CMPs, Chief Judge Stark held that Section 340B does not unambiguously support the agency's position—confirming the impropriety of CMPs, which are available only when a party *willfully* violates the law. *See Astrazeneca Pharms. LP v. Becerra*, No. CV 21-27-LPS, 2021 WL 2458063, at *10-11 (D. Del. June 16, 2021); 42 U.S.C. § 256b(d)(1)(B)(vi) (allowing for CMPs only where manufacturer "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price").

Second, on August 5, 2021, HRSA invited the National Association of Community Health Centers ("NACHC") to submit a new alternative dispute resolution ("ADR") petition against Sanofi that does not include claims against Eli Lilly & Company ("Lilly"). *See* Exhibit B. HRSA advised NACHC that it would not move forward with NACHC's pending ADR petition against Sanofi, AstraZeneca, and Lilly because the U.S. District Court for the Southern District of Indiana had preliminarily enjoined HRSA from implementing or enforcing the ADR Rule against Lilly. But as a workaround to the preliminary injunction, HRSA provided instructions to NACHC on how to submit a new ADR petition that excludes claims against Lilly. Following HRSA's guidance, NACHC filed an amended ADR petition against Sanofi and AstraZeneca on August 31, 2021. Sanofi has now been served with NACHC's amended petition, and an ADR panel could be assigned at any time. Sanofi thus faces an increased risk of being haled before an ADR panel to answer NACHC's amended ADR petition, even though the ADR Rule is legally invalid for the reasons argued by Sanofi in this Court.

In light of these two developments, Sanofi respectfully reiterates its request for an expedited ruling on the pending dispositive motions, to provide clarity about Sanofi's rights and obligations under Section 340B as well as regarding the validity of the agency actions challenged in this case.

Respectfully Submitted,

s/ Jennifer L. Del Medico

cc: All counsel of record